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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,269	02/17/2004	Keith M. Grispo	50319-00139	2232

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MARSH, FISCHMANN & BREYFOGLE LLP
8055 East Tufts Avenue
Suite 450
Denver, CO 80237

EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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10/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/780,269	Applicant(s) GRISPO, KEITH M.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57, 58 and 68-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57, 58 and 68-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/28/2009 has been entered.

Acknowledgments

1. This office action is in response to the reply filed on 9/28/2009.
2. In the reply, the Applicant amended cancelled claims 59-67 and added new claims 71-80.
3. Thus, claims 57-58, 68-80 are pending for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 57, 58, 68-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a "programmed purge

protocol” that advances first and second plunger drive rams of the injector to move plungers of the first and second syringes to purge air. The recitation of a programmed purge protocol that controls both syringes is at odds with the applicant’s originally filed specification. The original specification discloses that one of the heads (60b) controlling the saline solution is hand held (pg 21, Ins 15). The first head (60a) that controls the purging of the contrast syringe and solution is controlled by the programmed protocol and upon activation of the user by the purge button advances to a predetermined position (pg 22, Ins 1-8). But then in step 150, the user manually completes the purge sequence for the second syringe via head 60b (pgs 22, Ins 1-8). Next, in step 152, the user is again prompted to press or activate the purge button and once that happens, in step 154, head 60b for the saline syringe moves to a predetermined stop point forcing air from the tubing and connector (pg 22, Ins 9-17). In step 156, the user manually completes the purge sequence for the first syringe, using a manual knob or expel buttons, forcing any remaining air and/or gas from syringe and tubing and connector (pg 22, Ins 9-17).

4. First, it is unclear from the originally filed specification that the hand held head 60b is programmed or under any programmed control in any manner (see pg 20, Ins 11-13 “The ram of hand-held head 60b is actuated by a purge/retract trigger that moves the ram proportionally to the amount that the trigger is depressed” and citations above on pg 22, 1-8 regarding manual user action). Appropriate clarification is requested.

5. The claims recite that both plunger rams are under programmed control via the programmed purge protocol. Thus, both saline and contrast are delivered automatically

under programmed control without any user intervention. To that extent, the originally filed disclosure does not appear to disclose that action.

6. Appropriate clarification of the claims or record is requested. The examiner suggests reciting something along the lines of a memory, processor, and a computer readable have code that, when executed by a processor, actuates the plunger drive rams – where appropriate. And further suggests adding limitations denoting how and by what the saline syringe (that corresponds to hand-held head 60b) is actuated.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emig et al (6471674) in view of Medrad, Inc., "Stellant CT Injection System", Operation Manual Catalog #SOM 700 EN, 2003, 88 pages - hereafter, "Stellant".

2. Emig et al discloses a method of using a dual head injector (Fig 1), the method comprising: mounting a first syringe that is prefilled (300, col 2, lns 19-20; col 5, lns 38) with contrast media to the injector; mounting a second syringe to the injector (500); coupling a first section of T-tubing (450) to the first syringe and coupling a second section of the T-tubing to the second syringe (Fig 2a-f); initiating a programmed purge

protocol of the injector while the first and second syringes are mounted to the injector and while the first and second sections of the T- tubing are coupled to the first and second syringes (col 6, Ins 9-19); initiating a programmed purge protocol of the injector while the first and second syringes are mounted to the injector and while the first and second sections of the T- tubing are coupled to the first and second syringes (Fig 2a-f; col 6, Ins 6-18), respectively, wherein the first syringe comprises contrast media (300) prior to the initiation of the programmed purge protocol; wherein the programmed purge protocol comprises: advancing a first plunger drive ram of the injector to move a plunger of the first syringe to a first stop point at the intersection of the T-valve where the check valve and where the plunger of the first syringe stops (Fig 2a-f; col 6, Ins 6-18; wherein the plunger 320 is preferably advanced sufficiently to prime the fluid path between syringe 300 and check valve 410), wherein the advancing of the first plunger drive ram purges all air from the first syringe and the first section of Y-tubing and fills the first section of the Y-tubing with contrast media (Fig 2a-f; col 6, Ins 6-18; wherein the plunger 320 is preferably advanced sufficiently to prime the fluid path between syringe 300 and check valve 410); and advancing a second plunger drive ram of the injector to move a plunger of the second syringe to a second stop point where the plunger of the second syringe stops (Fig 2a-f; col 6, Ins 6-18; wherein the second stop clears everything with saline), wherein the advancing of the second plunger drive ram purges air from the second syringe and the second section and third sections of the T-tubing and fills it with saline (Fig 2a-f; col 6, Ins 6-18); and initiating a programmed injection procedure that includes injecting contrast media into the patient (col 6), wherein the programmed

injection procedure occurs: after the programmed purge protocol is completed; while the first and second syringes are mounted to the injector; and while the first and second sections of the Y-tubing are coupled to the first and second syringes, respectively (Fig 2a-g); wherein a combination of the advancing of the first plunger drive ram and the advancing of the second plunger drive ram results in a purge of substantially all air from the first and second syringes and the T-tubing (col 6); wherein the advancing of the first plunger drive ram occurs before the advancing of the second plunger drive ram (Fig 2a-f; col 6, lns 6-18); wherein the advancing of the second plunger drive ram comprises filling the second section of the Y-tubing with saline; wherein the advancing of the second plunger drive ram comprises filling the second section and a third section of the Y-tubing with saline (Fig 2a-f; col 6, lns 6-18); wherein the first syringe is filled with contrast media (300); wherein the second syringe comprises saline prior to initiating the programmed purge protocol (500).

4. However, Emig et al does not disclose a Y-connector.
5. Stellant teaches that it is known to have a Y-connector in a dual head injector system for the purpose of merging two flows into a single flow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the T-connector as taught by Emig et al with the Y-connector as taught by Stellant for the purpose of merging two flows because they perform substantially the same function in substantially the same manner.

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

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Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767